News from Ed Markey

United States Congress **Massachusetts Seventh District**

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Rep. Markey Urges FDA to "Leave No Stone Unturned and No Study Unexamined" in Analysis of Risky Drugs

Washington, D.C. – Rep. Edward J. Markey (D-MA), a senior Member of the Energy and Commerce Committee, today sent a letter to the Food and Drug Administration (FDA) urging the agency to launch a comprehensive review of all government sponsored studies that could possibly provide some insight into the safety and effectiveness of COX-2 inhibitors and NSAIDS.

"Following the recall of Vioxx and the conflicting information released about Celebrex, Aleve, and Bextra, many patients are confused about how to safely manage their pain." Rep. Markey said, "Part of the reason patients are confused, is that the government is confused. Although these drugs have been on the market for years, even the experts don't have all the answers as to the real risks and benefits of these drugs."

"Once drugs have been approved, there is often very little additional research regarding the safety or effectiveness of these drugs. In order to remedy this situation in the future, the FDA needs to revise its system of post-approval evaluation. However, consumers cannot wait for the FDA to change its policies to get some guidance on how to manage their pain. They need answers now."

"Over the years the federal government may have supported studies to examine these drugs for different uses. In December, after concerns were raised regarding the drug Celebrex, researchers turned to a large, ongoing three-year-old National Institutes of Health study which was designed to evaluate whether Celebrex and Aleve (naproxen) could help delay the onset of Alzheimer's disease. This review uncovered the potential problem with Aleve. If this analysis had never been conducted, we would still be in the dark with regard to the risks of Aleve."

"The answers to these difficult questions may lie in data that have already been collected by the government. The government can leave no stone unturned and no study unexamined in its analysis of these risky drugs. Once the FDA has some answers they need to quickly provide some guidance to consumers and health care professionals regarding the risks and benefits of these drugs."

For more information on Rep. Markey's work on FDA reform and copies of the letters sent to the FDA, please go to http://www.house.gov/markey/healthgen.htm

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